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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/781,173	02/18/2004	Gustavo C. Rodriguez	31140C	1808

7590 06/02/2006

Raymond N. Nimrod  
Roper & Quigg  
Suite 1000  
200 South Michigan Avenue  
Chicago, IL 60604

EXAMINER

GEMBEH, SHIRLEY V

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 06/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/781,173	<b>Applicant(s)</b> RODRIGUEZ ET AL.	
	<b>Examiner</b> Shirley V. Gembeh	<b>Art Unit</b> 1614	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 25 November 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 35-90 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 35-90 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

The response filed **November 25, 2005** presents remarks and arguments to the office action mailed **May 20, 2005**. Applicants' request for reconsideration of the rejection of claims in the last office action has been considered.

#### **Status of claims**

Claims 35-90 are pending.

Claims 37-38, 46-47, 55, 65-66, 75-77 and 85-86 are amended.

#### **Objection**

The objection to the specification has been withdrawn as Applicant has filed a certificate of correction and is granted and entered.

#### ***Claim Rejections - 35 USC § 112-first***

Claim 43-52, 55-62, 85-90 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant's arguments have been fully considered and persuasive.

The rejection is therefore withdrawn.

#### ***New Claim Rejections - 35 USC § 112-second***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claim 35-90 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

How is less frequently than daily defined? It is interpreted that less frequently than daily can mean once every other day, once a week, once every other month, once a year or a laundry list of other variation. How does one prevent administration of vitamin D via sunlight? A natural source of vitamin D. Does this mean that administration of vitamin D less frequently to any representative of females will induce apoptosis of non-neoplastic cells? What happens to a non-female representative that is administered vitamin D less than frequently that does not have ovarian non-neoplastic epithelium cells? Will the non-neoplastic cells die as well?

***Claim Rejections - 35 USC § 112-first***

With regards to Claim Rejections - 35 USC § 112 to claims 35-90 of prior office action the rejection is maintained, as stated in the office action, the instant claims does not reasonably provide enablement for a representative of vitamin D products to induce apoptosis in a large representation of females. The claim is very broad and include any female when given a representative of vitamin D will induce cell death-apoptosis in the non-neoplastic ovarian cells.

With regards to claims 43-90, the subject is not a female yet in the specification the only two examples are from a female with non-neoplastic ovarian epithelium cells, what happens to a male that does not have a non-neoplastic ovarian epithelium cells.

***Double Patenting***

The filing of the terminal disclaimer has been acknowledged by the examiner. The decision of the approval/disapproval is pending therefore the rejection will be maintained until the decision is made.

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shirley V. Gembeh whose telephone number is 571-272-8504. The examiner can normally be reached on 8:30 -5:00, Monday- Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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SVG

5/17/06

*Ardin H. Marschel 5/28/06*

**ARDIN H. MARSCHEL  
SUPERVISORY PATENT EXAMINER**